



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,633	07/25/2003	Gianni Guala	Q75566	9622
23373	7590	10/16/2006	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NIT

Office Action Summary	Application No. 10/626,633	Applicant(s) GUALA, GIANNI	
	Examiner Leslie R. Deak	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7 August 2006 has been entered.

Claim Objections

2. Claim 16 is objected to because of the following informalities: Claim 16 recites the limitations that the cap "is formed externally" with manual actuation parts. It is unclear whether applicant is claiming a method of forming a device or an additional structural limitation. Examiner has interpreted the claim to refer to a structural limitation. However, "formed externally" is unclear, and examiner is not sure what structure that limitation encompasses. Examiner has interpreted the claim to encompass a cap that has external ribs. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3761

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 13, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,360,404 to Novacek.

In the specification and figures, Novacek discloses the invention as claimed by applicant. With regard to claim 13, Novacek discloses a cannula or needle assembly 18 with a protection cap or needle guard 20. The cannula 18 has a hollow body or hub 22 with a luer connector that is adapted to be (considered by the examiner to be generally capable of) connecting with a corresponding luer connector in a fitting 26 (see column 5, lines 32-50, FIG1, see column 7, lines 39-61). The cannula 18 comprises a needle or tubular ferrule 21. The hub or hollow body 22 comprises lateral teeth 140, and the cap or needle guard 20 has complimentary lateral teeth 142 (see column 10, lines 28-59, FIGS 20-23). The hub or hollow body 22 and cap or guard 20 comprise a generally cylindrical shape (see FIGS 20, 21).

Applicant presents claim language drawn to the interaction between the teeth of the hub or hollow body and guard or cap when in use. Such statements are held by the examiner to be statements of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not distinguish from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Novacek specifically discloses that the teeth of the hub and the cap interact when the user torques the cap in a particular direction to apply rotation to the hub. When a torsional force is applied in the opposite direction, the cap may rotate freely around the hub, disengaging the cap from

Art Unit: 3761

the hub and allowing for removal of the cap from the hub (see column 3, lines 10-43).

Therefore, the Novacek device is capable of operating as claimed by applicant, meeting the limitations of the claims.

With regard to claim 14, the sawtooth-shaped ribs are interpreted by the examiner to be "axially tapered" since they taper in the direction perpendicular to the plane of the circular structure (see Merriam-Webster's Collegiate Dictionary, 10th ed., 2001).

With regard to claim 16, Novacek discloses that the cap may encompass ribs 100 on the surface of the cap (see FIG 32).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,360,404 to Novacek in view of US 4,883,470 to Haindl.

In the specification and figures, Novacek discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of an annular flange and a stop member in the cap. However, Haindl discloses a safety cap 10 for an injection cannula 21 that comprises ribs 15 that engage with wings 23 on the cannula hub 20 to provide torsional friction between the hub and the cap (see FIG 1, column 4, lines 22-

Art Unit: 3761

45). The ribs 15 on the cap extend to the inner border 16 of annular recess 17 (the border of the recess corresponds to applicant's flange). The flanged recess further comprises an annular bead 18 (corresponding to applicant's stop member) that engages with the cannula hub to provide a stop for the insertion depth of the hub into the cap to prevent damage to the cannula tip 22 (see column 4, lines 44-58). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the cannula hub and cap assembly disclosed by Novacek with the annular flange and stop member disclosed by Haindl in order to control the insertion depth of the cannula hub into the cap, preventing damage to the cannula tip, as taught by Haindl (see column 4, lines 44-58).

Response to Arguments

7. Applicant's arguments filed 7 August 2006 have been fully considered but they are not persuasive.

8. Applicant argues that the Novacek reference illustrates a conical hub and cap. While the parts may be conical, they also have a round shape, rendering them cylindrical and meeting the limitations of the claims.

9. Applicant further argues that the Novacek reference fails to disclose teeth formed on the outer surface of the hollow body or hub and the inner surface of the cap. However, Novacek clearly illustrates teeth 140 located on the outer surface of hub or hollow body 22 and corresponding teeth 142 on the inner surface of cap 20c (see FIGS 20-23).

Art Unit: 3761

Applicant further argues that the instantly claimed invention does not operate in the manner claimed by applicant. However, such an argument is directed to the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not distinguish from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Novacek specifically discloses that the teeth of the hub and the cap interact when the user torques the cap in a particular direction to apply rotation to the hub. When a torsional force is applied in the opposite direction, the cap may rotate freely around the hub, disengaging the cap from the hub and allowing for removal of the cap from the hub (see column 3, lines 10-43). Therefore, the Novacek device is capable of operating as claimed by applicant, meeting the limitations of the claims.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 4,237,882 Wickham
 - i. Needle sheath with tapered teeth

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
4 October 2006